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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/933,316

Applicant(s)

PORTER, STEPHEN C

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-11 and 15-41 is/are pending in the application.
- 4a) Of the above claim(s) 29-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-11,15-21,23-28 and 38-41 is/are rejected.
- 7) ☒ Claim(s) 39-40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/1/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed on March 01, 2004 has been entered. Claims 1-5, 7-11, 15-28, 38-41 read on the elected species and is under consideration. Claims 29-37 are withdrawn from further consideration for the reasons set forth in Paper Nos. 3, 5-6.

Any rejection that is not addressed in this Office Action is considered obviated in view of the Amendments or Arguments presented.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

2. Claims 1-5, 7-11, 15-21, 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krall et al WO 00/44287 (WO '287) in view of Evans US Patent 5,702,361.

Applicant's arguments with respect to this rejection filed on March 01, 2004 have been fully considered but they are not persuasive.

3. Applicant argues that Examiner's reliance on In re Kerkhoven, 205, USPQ 1069 (CCPA 198) ("Kerkhoven") to establish *prima facie* obviousness, is misplaced as the facts in Kerkhoven are distinguishable. Applicant goes on to say that Kerkhoven involved mixing of two known detergents which were known. Applicant then argues that one may not combine the compositions of the cited references, because the cited compositions of Evans work differently than those cited in WO '287. (see arguments at page 12).

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4. As the initial matter, Examiner responds that contrary to Applicant's assertion Kerkhoven is a case on point, as it sets forth obvious, the combining of two agents that are known in the art to be used for the same purpose. Kerkhoven, at 1072 citing In re Susi, 169 USPQ 423, 426 (CCPA 1971); In re Crockett, 126 USPQ 186, 188 (CCPA 1960). Accordingly, the legal test described in Kerkhoven focuses on the issue of combining agents that are known in the art and provide the same effects for the reasons of providing or improving the same effect as each would have provided. Nowhere in Kerkhoven or its precedent cases, does the legal test exploit mechanism of action of the ingredients involved in the combination. Therefore, applicant's arguments based on such notion are flawed. Examiner thus maintains the rejection of record and the reasoning based on Kerkhoven.

5. Even assuming *arguendo*, that mechanism of Action had played a role in forming the obviousness rejection in Kerkhoven. Still, Examiner's rejection is proper because contrary to Applicant's assertion, in Kerkhoven too, the detergent's used for the combination provided different mode of operation. In Kerkhoven, the Ruff reference employed anionic detergents and nonionic detergents. At the outset, the Court held that even combining such ingredients with the primary references that are not of such ingredients were ultimately an obvious modification in the art. Surely, at least the mechanism of action of an anionic detergent in Kerkhoven was not the same as the nonionic detergent employed therein. Therefore, contrary to applicant's contention, the fact that the compositions of Evans and WO '287 may work in different ways does not impart the instant compositions patentable over the cited references.

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6. Moreover, Applicant has selectively ignored the level of ordinary skill in the art of embolizing compositions and their knowledge for optimizing the amounts of suitable solvent as the carrier system of choice. Nowhere in Evans or even in WO '287 discourages the use of a solvent system with their polymeric or prepolymeric compositions. In fact, Wo '287 embraces the use of suitable biocompatible solvents for proper delivery of embolic agents. Such solvents include for example lower alcohols and also act as delivery carriers. (see Evans at col 6, lines 45-50). Also see WO '287 wherein, for example, at pages 39-40, the teaching of US Patent 5,925,683 is incorporated in WO '287. Further WO '287 embraces the use of embolizing agents of the art in conjunction with embolizing compositions (i.e. compositions of Evans). (see page 40, lines 10-15). Therefore, one of ordinary skill in possession of such art would have been able to ascertain the type and amount of solvents useful when combining the teachings of Evans with WO '287.

7. Finally, the scope of the instant claims does not in any way exclude the use of a solvent such as those taught by Evans. So Applicant's arguments on such basis are not commensurate with the scope of the claims and thus, are moot.

8. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

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reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Since the cited references are within the same filed of endeavour, combining their teachings are not based on hindsight reasoning, rather prima facie obviousness.

9. Here, both Evans and WO '287 teach administration of their composition into blood, they teach embolizing prepolymeric or polymeric composition and finally, achieve suitable in vivo embolization at a site of interest. Thus, combining their teachings would have been obvious.

10. The teachings of Krall WO '287 are described above. Krall fails to employ non-cyanoacrylate rheology modifying agents that are of polymeric material in amounts higher than 0% (as recited in claim 11) and/or have a specific molecular weight (as recited in claims 7-8).

11. Claims 1-3, 9-10, 15-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krall et al WO 00/44287 (WO '287) in view of Na et al US Patent 5,447,710.

12. Applicant has not substantially presented any arguments different than those responded above. Therefore, the claims are deemed obvious over the cited prior art and thus stand rejected for the reasons of record.

13. Claims 1-3, 9-10, 15-21, 23-28 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Krall et al WO 00/44287 (WO '287) in view of Krall US Patent 6,037,366 (US '366) for the reasons of record. Applicant has not presented any other arguments aside the ones that are addressed above.

Claim Objections

Claims 39-40 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The parent claim 3 requires the composition to further comprise a second nan-cyanoacrylate rheology-modifying agent comprising an inorganic particulate material. The dependent claims 39-40 allow such material to exist in amounts of about 0%. Therefore, claims 39-40 do not require existence of a second nan-cyanoacrylate rheology and fails to further limit the parent claim.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1, 3-5, 7-11, 15-16, 19, 26-27, 30, 38-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Hechenberger et al US Patent 4,997,861.

Hechenberger discloses all limitations of the instant claims. Hechenberger discloses a composition comprising monomeric alkyl cyanoacrylates that satisfy the instant matrix forming component, a poly acrylate that satisfies the instant element of polymeric non-cyanoacrylate rheology agent, and a stabilizer (see abstract; col 3, lines 29-col 4, line 40; claim 5). The prior art compositions also contain fumed silica in amounts of about 2-8% which satisfies the elements of claims 3, 37-41. The viscosity of Hechenberger's compositions falls within the instantly claimed ranges. (see col 2, lines 59-64). Accordingly, Hechenberger meets all elements of the instant claims.

Conclusion

15. No claims are allowed.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 3/1/2004 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

Directed to inorganic particulates species of claim 3, fumed silica.

1. Claims 1-3, 9-10, 14-21, 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krall et al WO 00/44287 (WO '287) in view of Na et al US Patent 5,447,710.
2. The teachings of Krall. Krall fails to address the limitations of claim 14 where the use of a non-cyanoacrylate rheology-modifying agent that comprises inorganic particles with surface-modifying molecules adsorbed to or bonded to the surface of such particles.
3. Na et al is merely used to show that nonionic surfactant may be administered as a surface modifier to be absorbed on the surface of diagnostic particles such as iodinated radiopaque agents. Na states that such modifications of radiopaque particles improve the particle size and quality of the contrast technique (see abstract; col 3, lines 35-40; col 5, lines 45-60; col 8, lines 1-30). Na teaches preparing his compositions in combination with other therapeutic ingredients (col 4, lines 44-56; col 7, lines 44-60). Na does not explicitly use his compositions in an embolic formulation.
4. However, as Na's iodinated contrast agents are similar to those taught in Krall WO '287, it would have also been obvious to one of ordinary skill in the art at the time of invention to substitute the radiopaque agents employed in Krall WO '287, with the surface modified iodinated contrast agents taught by Na, because Na suggests that the ordinary skill in the art would have had a reasonable expectation of success in improving the contrast properties of particulate containing compositions when such particles contain a surface modifier.

Claims 1-3, 6, 10, 12-16, 19-21, 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krall et al WO '287 in view of Greff US Patent 5,684,042 and Regan

The teachings of Krall are described above. Krall fails to teach inorganic particulate materials with surface-modifying molecules absorbed to it as set forth in the instant claim 14. However, the combination of Greff and Regan meets such deficiency.


Greff is used to show that for the purposes of adjusting viscosity of a prepolymeric cyanoacrylate formulations, inorganic particulate such as fumed silica or other alike thickening agents, are readily employed to achieve suitable viscosity for their *in vivo* delivery (see col 7, line 65-col8, line13). For example, Greff specifically teaches the use of fumed silica in producing gel type formulations. Further, applicant's attention is also drawn to Greff at col 7, lines 45-67. Accordingly, Greff indicates that polymerizable cyanoacrylate compositions can be easily formulated to a specific viscosity to meet disparate demands of the intended application of the composition. Therefore, employing suitable thickening agents, such as fumed silica or the like, would achieve similar flow properties in pre-polymerized cyanoacrylate compositions. Thus, for the purposes of optimizing viscosity of a cyanoacrylate formulation, thickening agents in general are viewed to be art equivalents, because they resolve the same problem and facilitate the same results. Greff, however, fails to specifically recite the use of surface modified inorganic particles, i.e. surface modified fumed silica, as a thickening agent.

Regan is merely used to show that surface modified fumed silica provides better thickening properties than fumed silica and that it improves rheological properties of aqueous solutions or dispersions of adhesive compositions of choice (see abstract, col 1, lines 55-58; col 5, lines 50-55). Therefore, for purposes of adjusting viscosity, surface modified fumed silica is a better choice than fumed silica.

The teachings of Krall, and Greff are considered to be in the same field of endeavor, because they teach prepolymeric alkyl cyanoacrylate compositions.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to add the inorganic particulates described in Greff, such as fumed silica to formulations of Krall, because the ordinary skill in art would have had a reasonable expectation of success in improving the viscosity of Krall's composition and subsequently enhancing the flow of the cyanoacrylate formulations of Krall for its intended use.

Furthermore, with respect to claim 14, Greff indicates that other alike thickening agents may be used in place of his fumed silica. Accordingly, since surface modified fumed silica provides better thickening properties than fumed silica of Greff, it would have been obvious to one of ordinary skill in the art at the time of invention to use the surface-modified fumed silica of Regan in place of fumed silica of Greff, because for the purposes of adjusting the viscosity of cyanoacrylate formulations, they are viewed to be functionally equivalent substitute and the ordinary skill in the art would have had a reasonable expectation to succeed in observing similar results.


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